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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/619,216   | 07/14/2003  | Laurent Verard       | 5074A0060CPA        | 7018             |
| 27572  | 7590        | 06/27/2007           | EXAMINER            |                  |
| HARNESS, DICKEY & PIERCE, P.L.C.<br>P.O. BOX 828<br>BLOOMFIELD HILLS, MI 48303 |             |                      | ROZANSKI, MICHAEL T |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
|  |             | 3768                 |                     |                  |
| MAIL DATE  |             | DELIVERY MODE        |                     |                  |
| 06/27/2007   |             | PAPER                |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/619,216             | VERARD ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Michael Rozanski       | 3768                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 May 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-66 is/are pending in the application.
  - 4a) Of the above claim(s) 35-43 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-34 and 44-66 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Arguments***

1. Applicant's arguments with respect to claims 1-66 have been considered but are moot in view of the new ground(s) of rejection.

***Election/Restrictions***

2. Applicant's election with traverse of claims 1-34 and 44-66 in the reply filed on 5/29/07 is acknowledged. The traversal is on the ground(s) that there is not a serious burden on the examiner. This is not found persuasive because the Groups I and II were distinguished when the telephonic requirement was made. Group II, which features an image guided navigation system including the generation and display of virtual images, involves 3D reconstruction techniques. The other independent claims in Group I feature navigation and gating in an image guided navigation system. Thus, the two groups would provide a serious burden on the examiner because Group I does not feature virtual image generation and display.

The requirement is still deemed proper and is therefore made FINAL.

***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

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F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 10/299,969. Although the conflicting claims are not identical, they are not patentably distinct from each other because Hunter et al. substantially claims all features in obvious alternate variations and groupings. Hunter et al. claims an image guided catheter navigation system for guiding a catheter through a region of a patient, comprising an imaging device selected from a number of imaging techniques, a tracking device, a controller, and a display. Hunter et al. also claims a method comprising receiving a cyclic physiological signal and time gating the detection of the location of the catheter, as well as time gating the generation of the image.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-13, 16-20, 44-49, and 51-66 are rejected under 35 U.S.C. 102(b) as being anticipated by *Kesten et al* (US 6,493,575).

**Claims 1-13, 16-20, 44-49, and 51-66:** Kesten et al disclose a catheter system 100 wherein a delivery catheter (figure 5A) is tracked through a region of a patient and is superimposed onto a live or previously acquired fluoroscopic image taken by a single or bi-plane c-arm fluoroscopy (electromagnetic) unit (col. 5, lines 58-67; col. 6, lines 17-50; figure 1). ECG is used in communication with computer workstation 102 to capture, store, and register images of the heart shape corresponding to periods during the cardiac cycle (col. 15, lines 53-66). The catheter is marked with radio-opaque markers, wherein the location of the markers is determined in the fluoroscopic image thereby tracking the catheter (col. 9, lines 48-60). The computer is operable to provide an estimated optimized site to navigate the instrument to (col. 3, lines 21-32). With regard to claim 20, the instrument is capable of being guided through a cerebrospinal fluid tree or vascular tree of the patient.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7, 14-16, 21, 22-24, 26-34, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kesten et al* in view of *Dumoulin et al* (US 5,377,678).

**Claims 7, 14-16, 21, 22-24, 26-34, and 50:** Kesten et al disclose a catheter system 100 wherein a delivery catheter (figure 5A) is tracked through a region of a patient and is superimposed onto a live or previously acquired fluoroscopic image taken by a single or bi-plane c-arm fluoroscopy (electromagnetic) unit (col. 5, lines 58-67; col. 6, lines 17-50; figure 1). ECG is used in communication with computer workstation 102 to capture, store, and register images of the heart shape corresponding to periods during the cardiac cycle (col. 15, lines 53-66). The catheter is marked with radio-opaque markers, wherein the location of the markers is determined in the fluoroscopic image thereby tracking the catheter (col. 9, lines 48-60). The computer is operable to provide an estimated optimized site to navigate the instrument to (col. 3, lines 21-32). A virtual 3D image can also be outputted since the fluoroscopic and fiber position are known (col. 7, lines 54-56).

With respect to claims 7 and 14-16, Kesten et al disclose an electromagnetic tracking device, but not one with a coil array and sensors associated with the instrument operable to sensor the electromagnetic field. In the same field of endeavor, Dumoulin et al teach a tracking unit 108, which provides power to the RF transmit coil to create a dipole electromagnetic field that is detected by RF receive coils 160 (col. 3, lines 1-4). The tracking is performed by a number of transmit coils situated on the invasive device

such as a biopsy needle (col. 1, lines 27-31), wherein the signals generated by the transmit coils are detected by a number of receive coils, which are electrical sensors, placed at known locations about the subject, and are registered and displayed by the display means (col. 3, lines 38-42). A number of transmit coils 30a, 30b, 30n are capable of being placed on an ultrasonic scanner in order to track the position of the imaging device (col. 3, lines 35-42; col. 7, lines 30-36). It would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated this feature because both references relate to tracking invasive devices in patients.

With regard to claim 21, the images of this tracking system may be obtained by a variety of different imaging modalities other than x-rays, such as ultrasound (col. 7, lines 30-36). It would have been obvious to one with ordinary skill in the art at the time the invention was made to incorporate ultrasound imaging because both references relate to tracking invasive devices in a patient.

8. Claims 22-24, 26-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Haddock* (US 2002/0077568) in view of *Dumoulin et al.*

**Claims 22-24, 26-30, and 32-33:** Haddock disclose an apparatus used to navigate a probe through an optimized site in a biological vessel with an accelerometer sensor 106 located on the tip of the catheter, whereby signal data is captured in control unit 202 that is connected to a computer 204 where data is analyzed and displayed as an image for 3D mapping (para. [00212-0027]). Haddock do not explicitly disclose use of superimposing an icon representing the instrument. In the same field of endeavor,

Dumoulin et al teach that the calculated position of the invasive device, such as a biopsy needle (col. 1, lines 27-31), is displayed by superposition of a symbol 152 on an x-ray image appearing on video monitor 151 (col. 4, lines 6-20). The tracking unit 108 taught by Dumoulin et al provides power to the RF transmit coil to create a dipole electromagnetic field that is detected by RF receive coils 160 (col. 3, lines 1-4). The tracking is performed by a number of transmit coils situated on the invasive device, wherein the signals generated by the transmit coils are detected by a number of receive coils, which are electrical sensors, placed at known locations about the subject, and are registered and displayed by the display means (col. 3, lines 38-42). It would have been obvious to one with ordinary skill in the art at the time the invention was made to incorporate superimposing in order to improve navigation of the instrument within the body.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Haddock* in view of *Dumoulin et al* and *Gilboa et al* (US 6,711,429).

**Claim 25:** Haddock and Dumoulin et al. disclose all claimed features of the current invention including an ultrasonic scanner (col. 7, lines 30-36) in Dumoulin et al, but do not specifically disclose the transducer operable to generate a Doppler effect. In the same field of endeavor, Gilboa et al. teach an ultrasound probe equipped with a 3D modeling algorithm capable of generating a Doppler effect for analyzing blood flow (col. 28, lines 1-6; col. 31, lines 1-6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Gilboa et al. to that of

Dumoulin et al. in order to enhance to imaging capabilities of the sensor by providing a way of analyzing hemo-dynamic physiological parameters.

10. Claim 31 and 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Haddock* in view of *Dumoulin et al* and *Kesten et al*.

**Claim 31 and 34:** Haddock and Dumoulin et al. disclose all features, but do not claim sensing physiological event gated to image data. In the same field of endeavor, Kesten et al teach that ECG is used in communication with computer workstation 102 to capture, store, and register images of the heart shape corresponding to periods during the cardiac cycle (col. 15, lines 53-66). It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teaching of Kesten et al in order to provide improved gated images.

#### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*MR*

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